

SPECIAL 510(K) PREMARKET SUMMARY

K110582

VALO® Cordless

APR 28 2011

This summary of the Special 510(k) substantial equivalence information is being submitted in accordance with the requirements of 21 CFR 807 for VALO® Cordless.

Applicant's Name and Address

Ultradent Products, Inc.
505 West 10200 South
South Jordan, UT 84095

| | |
|------------------------|----------------------------------|
| Contact Person: | Diane Rogers |
| Title: | Regulatory Affairs Manager |
| Telephone: | 800-552-5512 x4491, 801-553-4491 |
| FAX: | 801-553-4609 |
| Date Summary Prepared: | April 1, 2011 |

Name of the Device

| | |
|------------------------------|---|
| Trade Name: | VALO® Cordless |
| Common Name: | Activator, ultraviolet for polymerization |
| Device Classification: | II |
| Classification Product Code: | EBZ |

Legally Marketed Predicate Device to Which Equivalence is Claimed

The predicate device is VALO® (K083647). This device is manufactured and distributed by Ultradent Products, Inc., 505 West, 10200 South, South Jordan, Utah 84095.

Product Description: Valo® Cordless is a visible light activator for polymerization of dental resins. In other words, it is a dental curing light used for polymerization of all photo-initiated dental materials. The VALO Cordless is shipped as a system with the VALO Cordless wand, 4 rechargeable batteries, 2 for initial use and 2 for later use, a battery charger and 50 VALO Cordless Barrier Sleeves. An Instruction for Use is also included inside the packaging. The Instructions for Use details the function of the device and describes the modes for the VALO Cordless. VALO Cordless has three operating modes. They are Standard Power Mode: 1000mW/cm², High Power Mode: 1400mW/cm² and Xtra Power Mode: 3200mW/cm².

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Indications for Use: Source of illumination for curing photo-activated dental restorative materials and adhesives.

Technological Summary: The VALO CORDLESS curing light uses a custom, multi-wavelength Light Emitting Diode (LED) for producing the high intensity light (395 - 480 nm) capable of polymerizing all light cure dental materials. This intensity will also penetrate porcelain and is capable of curing underlying resin cements similarly to a quality halogen light.

The VALO CORDLESS curing light uses safe Ultradent VALO rechargeable batteries and battery charger.

Performance Data:

| | VALO CORDLESS Curing Light |
|------------------|---|
| Wavelength range | <p>395nm -- 480nm (see qualification below)</p> <p>Effective output Power of VALO CORDLESS falls within the following wavelength range:</p> <ul style="list-style-type: none"> 395nm <= EP <= 480nm. <p>Minimal and insignificant power can be found in wavelength ranges from:</p> <ul style="list-style-type: none"> 380nm – 395nm and 480nm – 510nm <p>ADA 48 specifies power limitations within specific wavelength bands. The VALO CORDLESS complies with ADA 48</p> |
| Light intensity | <p>* Standard power – 1000mw/cm2 +/-10%</p> <p>* High power – 1400mw/cm2 +/-10%</p> |

| | |
|--|--|
| | <p>† Xtra Power – 3200mw/cm2 +/- 20% (formerly called 'Plasma Emulation')</p> <p>* As measured by a Demetron® L.E.D, Radiometer</p> <p>‡ As measured by a spectrum analyzer</p> <p>Den-Mat® Sapphire Plasma Arc Curing Light – Irradiance measured at 2,600mW/cm2 with a spectrum analyzer</p> |
|--|--|

The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601-1 Electrical Safety.

Conclusion:

Comparison Table

| | VALO® (K083647) | VALO® Cordless |
|----------------------------|--|--|
| Power Supply | Wall powered, 12VDC, medical grade with adapters for International capability UL Approved | Same |
| Indications For Use | Source of illumination for curing photo-activated dental restorative materials and adhesives. | Same |
| Structure | Ergonomic wand | Same |
| Light | Blue and UV wavelengths | Same |
| Current control | Regulates current in the light source | Same |
| Buttons | Two buttons that function the light | Same |
| Power ON button | Located on handle of wand | Same |
| Power cord | 8' length | Same |
| Time | Device indicates time and time selection | Same |
| Power Rating | Plasma Emulation Mode is 4500mW/cm ² | Xtra Power mode is 3200mW/cm ² |
| Operation | 110VAC | 110VAC |

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Substantial Equivalence:

The VALO™ SCOUT is substantially equivalent to the VALO™ which is also manufactured by Ultradent Products, Inc. These two products are manufactured from the same materials, utilize many of the same components, are calibrated to the same levels and parameters, are used in the same manner and fashion, and are designed to operate and function in a near identical manner. The VALO™ SCOUT was designed to be the VALO™ but without the cord. The programming code is near identical, save micro-controller variations and enhanced safety features. Both products have the same intended use and technological characteristics. Both products are safe and effective when used for as intended and for the purposes described. The following three tests were conducted along with bench tests described in the 510(k); depth of cure, software verification and validation and IEC 60601 Electrical Safety.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Ms. Diane Rogers
Regulatory Affairs Manager
Ultradent Products, Incorporated
505 West 10200 South
South Jordan, Utah 84095

APR 28 2011

Re: K110582
Trade/Device Name: VALO® Cordless
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: April 1, 2011
Received: April 5, 2011

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'A. D. Watson'.

Anthony D. Watson, B.S., M.S., M.B.A.
Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K110582

Device Name: VALO® Cordless

Indications for Use:

Source of illumination for curing photo-activated dental restorative materials and adhesives.


Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110582

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(Posted November 13, 2003)